REMARKS/ARGUMENTS

I. Status of the Claims

Claims 1-6, 10, 21 and 68-79 are currently pending, with claims 10, 21, 70-72 and 74-79 withdrawn from consideration as directed to a non-elected invention. Upon entry of this amendment, claim 1 is amended without prejudice or disclaimer.

II. Elections/Restrictions

The Office has denied the request made in the response filed on July 16, 2003 to consider the claims in Groups I-IV together. Reconsideration of this decision is respectfully requested.

The Office Action asserts that the restriction is proper notwithstanding the case law cited in the July 16th response because the CCPA decisions cited in the response (i.e., *In re Weber, Soder and Boksay* 198 USPQ 328, 331 (C.C.P.A., 1978)) allow for such a restriction so long as the restricted claims in aggregate encompass the full scope of the original claim. This is a misreading of the decision. The decision simply uses for illustrative purposes the scenario in which restriction of a single claim results in fragmentary claims that do not necessarily correspond to the original claim to demonstrate one example of why the courts have established the general rule that single claims cannot be restricted into multiple groups. The basic rule, as pointed out in the last response, is clear:

> The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- no matter how broad, which means no matter how many independently patentable inventions may fall within it.

See, In Re Weber, Soder and Boksay at 334.

To reiterate a point in the last response, the Office can require a species election if initial examination is deemed unduly burdensome. This is approach is appropriate because it strikes an appropriate balance between the concerns of the Office regarding unduly burdensome

examination and the clear constitutional and statutory right of an inventor to claim an invention as it is contemplated. It would thus be acceptable under exiting case law if the Office removed the restriction requirement with respect to Groups I-IV and imposed a species election with respect to the claims in these four groups. Instead the Office has restricted individual claims *and* then still imposed a species election requirement.

If the Office persists in maintaining the restriction with respect to Groups I-IV, then it is submitted that the provisions of MPEP 609 are applicable. This section of the MPEP states that in cases in which there is a linking claim and a restriction requirement has been imposed, that the restriction requirement must be withdrawn if it is determined that a linking claim is allowable. It is submitted that claims 1-6 and 69 are linking claims that link the claims in each of Groups I-IV. It is thus requested that the restriction requirement be withdrawn should one of these linking claims be found allowable as required under the provisions set forth in MPEP 609.

As a somewhat separate, but nonetheless related consideration, it is noted that the current claims are rejected only on non-prior art grounds. It is thus assumed that the claims in the elected group have been fully examined across their breadth, in particular that the claims in the elected group have been examined with respect to each of the species within the elected group, as required under MPEP 803.02. If this is not the case, it is requested that examination continue with respect to each species in the elected group until either prior art that renders the claim unpatentable is identified or until it is determined that there is no prior art with respect to the species in the elected group.

III. Claim Rejections under 35 U.S.C. 112

A. New Matter

Claims 1-6 and 68, 69 and 73 are rejected under 35 U.S.C. 112, first paragraph because the original specification is said not to discuss methods for detecting CD1a levels in blood, plasma, serum or urine sample. The claims are thus said to introduce new matter. Applicants respectfully disagree.

As an initial matter, it is noted that the claims have been amended to refer to detection of the protein marker in a blood sample. The issue with respect to plasma, serum and urine is thus rendered moot. It is further noted that the specification states in several sections that methods can be conducted with blood samples (see, e.g., page 7, line 33; page 57, lines 9 and 12; and page 58, line 5). It is thus submitted that the claims are fully supported by the original specification. Accordingly, it is requested that this rejection be withdrawn.

B. Enablement

The Office Action also asserts that claims 1-6, 68, 69 and 73 fail to comply with the enablement requirement. The Office Action provides three primary rationales to support this conclusion: 1) that CD1a not likely be detectable in serum or urine and that it would not likely be detectably different in individuals with macular degeneration as compared to individuals in a control group; 2) that the specification does not provide any guidance as to the levels of CD1a in samples such as blood and how the levels change in diseases such as aneurysm and macular degeneration; and 3) that it is illogical for the method to require as a pre-requisite the type of determination that the method itself is suppose to make.

With respect to the first rationale, it is first noted that the claims have been amended to indicate that the sample is a blood sample. The issue thus becomes whether CD1a can be detected in the blood. The van der Wel et al. article (Mol. Biol. Cell 14: 3378-3388, 2003) cited in the Office Action explicitly confirms that CD1a is present in blood, stating that dendritic cells expressing CD1a are present in blood (see, e.g., introduction). As also noted in the Office Action itself and in other references cited by the Office (see, e.g., Davison college datasheet), CD1a is expressed on the *surface* of dendritic cells. Accordingly, CD1a can be detected in the blood.

To support the contention that CD1a levels would not likely differ between individuals with aneurysm and those without, the Office Action cites to the van der Well article, which is said to indicate that CD1 cell surface expression was not detectably increased during maturation of dendritic cells. But for at least two reasons this article does not address the real issue, namely whether there is a change in CD1a levels in individuals with aneurysm and those

without. First, the article reports conclusions from studies conducted only with respect to CD1b and CD1c, not CD1a, during dendritic cell maturation (see, e.g., abstract and discussion section). This article does not specifically address CD1a expression. Second, this article simply focuses on the trafficking of CD1b and CD1c in immature versus mature dendritic cells. There is no discussion whatsoever regarding how CD1 molecules of any type might be affected in individuals with aneurysm or macular degeneration versus those without.

With regard to the second issue, it is submitted that one of ordinary skill in the art can readily practice the currently claimed invention without undue experimentation and that the claim includes a basis for determining whether the level of a protein marker (e.g., CD1a) is such that the level is indicative of risk of aortic aneurysm at a location other than the eye. As set forth in claim 1, the presently claimed invention generally involves (1) detecting one or more of the recited protein markers (e.g., CD1a) in a blood sample, and (2) determining if the level of the marker(s) differs from the level of the same marker(s) in a control population.

It is submitted that one of skill can perform both of these analyses without undue experimentation. With respect to analysis (1), a variety of methods were known in the art as of the priority date of this application to detect proteins in blood samples (e.g., immunological methods, see, e.g., page 56, line 26-27 and line 30). Analysis (2) likewise could also be readily preformed by those of ordinary skill as of the priority date of this application because it simply involves comparing the value determined in (1) with the level for a control population (e.g., a historic value determined previously).

It appears that the Examiner's primary concern may be that after performing the current method that not all individuals that show a protein marker level that differs from that of the control population will have an aneurysm or develop an aneurysm. But the claim does not require such an absolute correlation. The claim instead is directed to evaluating an individual's risk for aortic aneurysm. Thus, the claimed methods may, for example, serve as a preliminary screening tool to identify individuals at increased risk who can then be evaluated using other techniques to make a final determination as to their actual condition. But the current methods are nonetheless still valuable because many methods for detecting the presence of aneurysms are

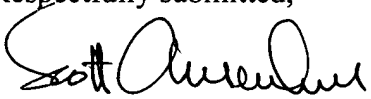
not readily amenable to the screening of large populations (see, e.g., page 3, lines 30-34), whereas the claimed methods are.

The final concern expressed in the Office Action is with respect to the statement that the control population includes at least one individual that does not have an aortic aneurysm or macular degeneration. The Office views this as illogical because it involves making the same determination that the claimed method is supposed to make. In response it is submitted that an appropriate control group could be identified in a number of different ways. The application, for example, discusses a number of established medical procedures that can be utilized to detect the presence or absence of aneurysm (see, e.g., page 3, lines 30-33). Marker levels in the blood from such individuals, for example, could be used to establish the level of these markers for the control population. The claim should not be interpreted to suggest that an analysis for the control population must be made contemporaneously with respect to the analysis of the test subject's blood. As is common in the art, the level for the control population can, for example, be based upon historic data (i.e., data determined prior to the current analysis of the subject's blood).

So for all the foregoing reasons it is submitted that the currently claimed methods could be readily conducted without undue experimentation. As such, it is submitted that the claims are enabled and that the rejection should be withdrawn.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,



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